1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
  - **Trade name:** PrimaDry™
  - **Article number:** 10955
  - **Index number:** SDS 65-001.09
- **Relevant identified uses of the substance or mixture and uses advised against**
  - Professional Dental Priming Agent
- **Application of the substance / the mixture**
  - Professional Dental Priming Agent
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    - Ultradent Products Inc.
    - 505 W. Ultradent Drive (10200 S)
    - South Jordan, UT 84095-3942
    - USA
        - onlineordersupport@utradent.com
  - **EC Responsible Person**
    - Ultradent Products GmbH
    - Am Westhover Berg 30
    - 51149 Cologne Germany
    - Email: infoDe@utradent.com
    - Emergency Phone: +49(0)2203-35-92-0
  - **Further information obtainable from:**
    - Customer Service
    - **Emergency telephone number:**
      - CHEMTREC (NORTH AMERICA) : (800) 424-9300
      - (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  - GHS02 flame
  - Flam. Liq. 2  H225 Highly flammable liquid and vapour.

- **GHS07**
  - Skin Irrit. 2  H315  Causes skin irritation.
  - Eye Irrit. 2  H319  Causes serious eye irritation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms**
  - GHS02, GHS07
- **Signal word**
  - Danger

(Contd. on page 2)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: PrimaDry™

Hazard statements
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

Composition/information on ingredients
Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

| CAS: 64-17-5 | Ethyl Alcohol | Flam. Liq. 2, H225 | >50-≤100%
| EINECS: 200-578-6 | Trade Secret | Skin Corr. 1A, H314 | ≤1%

Additional information: For the wording of the listed hazard phrases refer to section 16.

First aid measures
Description of first aid measures
General information: Immediately remove any clothing soiled by the product.
After inhalation: In case of unconsciousness place patient stably in side position for transportation.
After skin contact: Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing: If symptoms persist consult doctor.
Information for doctor:
Most important symptoms and effects, both acute and delayed: No further relevant information available.
Indication of any immediate medical attention and special treatment needed: No further relevant information available.
5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
  CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** Carbon monoxide (CO)
- **Advice for firefighters:**
- **Protective equipment:**
  Wear self-contained respiratory protective device.
  Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
- **Reference to other sections**
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:** Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:**
  Keep ignition sources away - Do not smoke.
  Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
  - **Information about storage in one common storage facility:** Not required.
  - **Further information about storage conditions:**
    See product labelling.
    Keep container tightly sealed.
    Store in cool, dry conditions in well - sealed receptacles.
- **Specific end use(s)** Professional Dental Priming Agent

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
48. Control parameters

- Ingredients with limit values that require monitoring at the workplace:
  - 64-17-5 Ethyl Alcohol
  - WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm

- Additional information: The lists valid during the making were used as basis.

- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    - Keep away from foodstuffs, beverages and feed.
    - Immediately remove all soiled and contaminated clothing.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
  - Respiratory protection: Not required.
  - Protection of hands:
    - Protective gloves
    - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  - Material of gloves
    - The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  - Penetration time of glove material
    - The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - Eye protection:
    - Tightly sealed goggles

- Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
  - Appearance:
    - Form: Liquid
    - Colour: Yellow tint
    - Odour: Alcohol-like
    - Odour threshold: Not determined.
  - pH-value: Not determined.
  - Change in condition
    - Melting point/freezing point: -100 °C
**Initial boiling point and boiling range:** 78 °C

- **Flash point:** 13 °C
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** 363 °C
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Explosion limits:**
  - **Lower:** 3.3 Vol %
  - **Upper:** 19 Vol %
- **Vapour pressure at 20 °C:** 552 hPa
- **Density at 20 °C:** 0.79 g/cm³
- **Relative density:** Not determined.
- **Vapour density at 20 °C:** 1.6 g/cm³
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with water at 20 °C:** 1,000 g/l
- **Partition coefficient: n-octanol/water:** Not determined.

**10 Stability and reactivity**

- **Reactivity:** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** Flammable.
- **Conditions to avoid:**
  - Ignition sources
  - Sparks
  - Flames
  - Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
12 Ecological information

- Toxicity

- Aquatic toxicity:

  64-17-5 Ethyl Alcohol

  Algae Toxicity 1,000 mg/l (Algae)

  - Persistence and degradability: No further relevant information available.
  - Behaviour in environmental systems:
    - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
  - Additional ecological information:
    - General notes:
      Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
      Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation: Do not allow product to reach sewage system.

- European waste catalogue

  HP 3 Flammable
  HP 4 Irritant - skin irritation and eye damage
### 14 Transport information

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Information</th>
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<td>UN1987</td>
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<td><strong>ADR, IMDG, IATA</strong></td>
<td>1987 ALCOHOLS, N.O.S. (Ethyl Alcohol)</td>
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<td><strong>UN proper shipping name</strong></td>
<td>ALCOHOLS, N.O.S. (Ethyl Alcohol)</td>
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<tr>
<td><strong>ADR</strong></td>
<td>3 Flammable liquids.</td>
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<tr>
<td><strong>IMDG, IATA</strong></td>
<td>3</td>
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<tr>
<td><strong>Packing group</strong></td>
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<tr>
<td><strong>Environmental hazards:</strong></td>
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<td><strong>Special precautions for user</strong></td>
<td>Warning: Flammable liquids.</td>
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<tr>
<td><strong>Danger code (Kemler):</strong></td>
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<tr>
<td><strong>EMS Number:</strong></td>
<td>F-E,S-D</td>
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<tr>
<td><strong>Stowage Category</strong></td>
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<td><strong>Transport in bulk according to Annex II of Marpol and the IBC Code</strong></td>
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<td><strong>Limited quantities (LQ)</strong></td>
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<tr>
<td><strong>Excepted quantities (EQ)</strong></td>
<td>Maximum net quantity per inner packaging: 30 ml</td>
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<tr>
<td></td>
<td>Maximum net quantity per outer packaging: 500 ml</td>
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<tr>
<td><strong>Transport category</strong></td>
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<tr>
<td><strong>Tunnel restriction code</strong></td>
<td>D/E</td>
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<tr>
<td><strong>IMDG</strong></td>
<td>1L</td>
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<tr>
<td><strong>UN &quot;Model Regulation&quot;:</strong></td>
<td>UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, II</td>
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</tbody>
</table>

(Contd. of page 6)
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Seveso category P5c FLAMMABLE LIQUIDS
  - Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
  - Chemical safety assessment:
    Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
  H225 Highly flammable liquid and vapour.
  H314 Causes severe skin burns and eye damage.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service

- Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  VOC: Volatile Organic Compounds (USA, EU)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Flam. Liq. 2: Flammable liquids – Category 2
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2